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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
097712,615	11/13/00	BUECHLER	K 230/006

HM12/0403

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EXAMINER

COOK, L

ART UNIT	PAPER NUMBER
1641	3

DATE MAILED: 04/03/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/712,615

Applicant(s)

BUECHLER ET AL.

Examiner

Lisa V. Cook

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1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 13 November 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 6, 7, 16, 17, 27-47, and 54-92 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 6, 7, 16, 17, 27-47, and 54-92 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 6 and 7 are drawn to an apparatus and kit for determining a rate of flow of a solution comprising members of a binding pair (MBP), wherein an optical signal is detected, classified in class 436, subclass 63.
  - II. Claims 16 and 17 are drawn to an apparatus and kit for determining environmental conditions in an assay comprising members of a binding pair, wherein an optical signal is detected, classified in class 436, subclass 63.
  - III. Claims 27 and 28 are drawn to an apparatus and kit for measuring progress and time of completion for an assay employing a device comprising a reaction chamber, discrete zone, and diagnostic lane, classified in class 436, subclass 63.
  - IV. Claims 29-36 are drawn to a method, an apparatus and kit for determining deviant assay results in an assay device comprising the evaluation of assay signals (AS) and independent assay control signals (IACS), classified in class 436, subclass 63.
  - V. Claims 37-47 are drawn to a method, an apparatus and kit for smoothing assay signal determinations in an assay device comprising the evaluation of members of a binding pair (MBP) and affinity tag partners (ATP), classified in class 436, subclass 63.
  - VI. Claims 54 and 55 are drawn to an apparatus and kit for verifying a location of a detection zone in an assay device, classified in class 436, subclass 63.

- VII. Claims 56-63 and 65 are drawn to a method along with the corresponding apparatus for determining a corrected assay result ( $T_c$ ) from a measured assay result ( $T_m$ ) and multiple ( $j$ ) measured control assay results ( $IAC_j$ ) via a difference between  $IAC_j$ ,  $IAC_{jave}$ ,  $IAC_{ji}$  multiplied by  $\beta_j$ , classified in class 435, subclass 334.
- VIII. Claims 64 is drawn to computer readable storage medium for determining a corrected assay result ( $T_c$ ) from a measured assay result ( $T_m$ ) and multiple ( $j$ ) measured control assay results ( $IAC_j$ ) via a difference between  $IAC_j$ ,  $IAC_{jave}$ ,  $IAC_{ji}$  multiplied by  $\beta_j$ , classified in class 700, subclass 90.
- IX. Claims 66-74 and 76 are drawn to a method along with the corresponding apparatus for determining a corrected assay result ( $T_c$ ) from a measured assay result ( $T_m$ ) and multiple ( $j$ ) measured control assay results ( $IAC_j$ ) via a difference between  $\delta IAC_j$ ,  $IAC_j$ ,  $IAC_{jave}$ ,  $IAC_{ji}$  multiplied by  $T_j$ , classified in class 435, subclass 334.
- X. Claim 75 is drawn to computer readable storage medium for determining a corrected assay result ( $T_c$ ) from a measured assay result ( $T_m$ ) and multiple ( $j$ ) measured control assay results ( $IAC_j$ ) via a difference between  $\delta IAC_j$ ,  $IAC_j$ ,  $IAC_{jave}$ ,  $IAC_{ji}$  multiplied by  $T_j$ , classified in class 700, subclass 90.

- XI. Claims 77-82 and 84 are drawn to a method along with the corresponding apparatus for determining a corrected assay result ( $T_c$ ) from a measured assay result ( $T_m$ ) and multiple ( $j$ ) measured control assay results ( $IAC_j$ ) via the  $T_m$  measurement of each  $IAC_j$ , a sum of the integer 1 of each function  $IAC_j$ , and a quotient between  $T_m$  and the sum, classified in class 435, subclass 334.
- XII. Claim 83 is drawn to computer readable storage medium for determining a corrected assay result ( $T_c$ ) from a measured assay result ( $T_m$ ) and multiple ( $j$ ) measured control assay results ( $IAC_j$ ) via the  $T_m$  measurement of each  $IAC_j$ , a sum of the integer 1 of each function  $IAC_j$ , and a quotient between  $T_m$  and the sum, classified in class 700, subclass 90.
- XIII. Claims 85-90 and 92 are drawn to a method along with the corresponding apparatus for determining a corrected assay result ( $T_c$ ) from a measured assay result ( $T_m$ ) and measured independent control assay results ( $IAC$ ) via the  $T_m$  measurement of each  $IAC$ , determining a quotient mean value ( $IAC_{ave}$ ) of multiple  $IAC$  measurements ( $IAC_i$ ) multiplied by  $T_m$ , classified in class 435, subclass 334.
- XIV. Claim 91 is drawn to computer readable storage medium for determining a corrected assay result ( $T_c$ ) from a measured assay result ( $T_m$ ) and multiple ( $j$ ) measured control assay results ( $IAC_j$ ) via the  $T_m$  measurement of each  $IAC$ , determining a quotient mean value ( $IAC_{ave}$ ) of multiple  $IAC$  measurements ( $IAC_i$ ) multiplied by  $T_m$ , classified in class 700, subclass 90.

2. The inventions are distinct, each from the other because of the following reasons:

A. Inventions I-VII, IX, XI, and XIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different methods, apparatus, and kits of inventions I, II, III, IV, V and VI are patently distinct. Each of the inventions perform different functions, wherein they evaluate different end points. Group I detect a rate of flow, Group II detects environmental conditions, Group III detects progress and time of completion, Group IV detects deviant assay results, Group V smoothes assay signals, while Group VI verifies a location in an assay device. Each of the inventions are divergent and independent with respect to function, operation, or effect. Therefore, they are patently distinct.

Although, inventions VII, IX, XI, and XIII although they detect the same effect have different modes of operation. Because all the methods have different method steps, employing different reagents, they are independent and separate methods/apparati inventions from each other and the other inventions (I-VI).

B. Inventions (VII, IX, XI, XIII) and (VIII, X, XII, XIV) are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the methods/apparatus of inventions VII, IX, XI, or XIII are not limited to the particular computerized analysis/computer readable storage mediums of invention VIII, X, XII, and XIV. Such analysis can be done manually (by hand) with optical systems and written data recordings.

C. Inventions I-VI and (VIII, X, XII, XIV) are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the computer readable storage mediums have not utility in the different method/apparatus inventions of Groups I-VI.

3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Please note that the classifications in the restriction are illustrative only and **do not** represent all the classes and subclasses which must be searched for each invention; nor is the search limited to issued US patents, but rather includes foreign patents and applications as well as literature searches.

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4. A telephone call was made to Michael A. Whittaker (Reg. No.46,230) on 3/28/01 to request an oral election to the above restriction requirement, but did not result in an election being made.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

7. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO fax center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 Fax number is (703) 308-4242 which is able to receive transmissions 24 hours/day, 7 days/week.

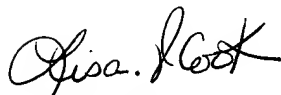
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (703) 305-0808. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.



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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (703) 305-3399.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.




*Lisa V. Cook*

*Patent Examiner*

*Art Unit 1641*

*CM1-7B17*



CHRISTOPHER L. CHIN  
PRIMARY EXAMINER  
GROUP ~~1800~~ 1641